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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,850	11/13/2003	Donald L. Durden	1857-ART1.0024US-CON	8658
110 7590 04/17/2008 DANN, DORIMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307				
EXAMINER				
YU, MISOOK				
ART UNIT		PAPER NUMBER		
1642				
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04/17/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/712,850

Applicant(s)

DURDEN, DONALD L.

Examiner

MISOOK YU

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2007 and 08 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 91-94, 96, 98-100, 102, 104-106, 108, 110-112 and 115-121 is/are pending in the application.
- 4a) Of the above claim(s) 115-119 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 91-94, 96, 98-100, 102, 104-106, 108, 110-112 is/are rejected.
- 7) ☒ Claim(s) 120 and 121 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Claims 115-119 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 91-94, 96, 98-100, 102, 104-106, 108, 110-112, 115-121 are pending, and claims 91-94, 96, 98-100, 102, 104-106, 108, 110-112, 120, and 121 are under consideration.

Claim Rejections - 35 USC § 112, Withdrawn

The rejection of the claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of the amendment.

The rejection of the under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **withdrawn** in view of the amendment.

The rejection of the claims rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method using LY294002 and Wortmannin, and TNF alpha for effectively inhibiting aberrant tumor-associated angiogenesis, does not reasonably provide enablement for any other PTEN agonist, PI3 kinase inhibitor, AKT inhibitors is **withdrawn** in view of the amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 91, 92, 96, 98, 104, and 110-112 are rejected under 35 U.S.C. 102(a) as being anticipated by Hu et al (March 2000, Clinical Cancer Research, vol. 6, pages 880-886) as evidenced by Jiang et al (02-15-2002, PNAS vol. 97, pages 1749-1753).

Applicant argues that Hu et al., demonstrate LY294002 was effective to by exerting toxic effect directly, or increase apoptosis of ovarian carcinoma, or inhibits cell cycle but do not teach the tumor reduction was to due inhibition of aberrant tumor-associated angiogenesis. Applicant also argues that Jiang et al., showed angiogenesis inhibition in embryonic angiogenesis, a system completely unrelated to tumor formation. Applicant also argues that new claims 120 and 121 recites positive step of monitoring microvessel density and assessing the inhibition of angiogenesis.

These arguments have been fully considered but found unpersuasive for the following reasons:

There are two manipulative steps (selection of patient and administering the active agent) to practice the claimed invention in claims 91, 92, 96, 98, 104, and 110-112. In order to remove Hu et al., as the prior art, the patient population and/or the active agent in the claimed invention should be different. Note claims 91, 92, 96, 98, 104, and 110-112 do not require monitoring whether or not the active agent has any effect on microvessel density or assessing inhibition of angiogenesis. Since the active agent and population of patients being treated are same, it is concluded that the active

agents must have the recited function. In addition, the instant specification in the summary of prior art, for example, in Paragraph [0008] reasonably communicates a solid tumor progression is dependent on the induction of angiogenic signals, thus the progression of solid tumor of Hu et al., required angiogenic signals and reduction of tumor must have been in part due to inhibition of angiogenesis. This rejection would be obviated if the tumor-bearing mice of Hu et al, are not same as "a patient in need thereof" in claim 91.

As for arguments with the limitations of claims 120 and 121, it is concluded that applicant is arguing limitations not present in the rejected claims.

Claims 91 and 110 are rejected under 35 U.S.C. 102(b) as being anticipated by Schultz et al., *Anticancer Res.* 1995 Jul-Aug;15(4):1135-9, as evidenced by Oikawa et al (1996, *European Journal of Pharmacology*, vol. 318, pages 93-96) discloses Wortmannin inhibits angiogenesis.

Applicant argues that Schultz et al., like Hu et al., above fail to teach a role for Wortmannin in tumor-associated angiogenesis.

This argument has been fully considered but found unpersuasive.

Since the active agent and population of patients being treated are same, it is concluded that the active agents must have the recited function. In addition, the instant specification in the summary of prior art, for example, in Paragraph [0008] reasonably communicates a solid tumor progression is dependent on the induction of angiogenic signals, thus the progression of solid tumor of Shultz et al, required angiogenic signals and reduction of tumor must have been in part due to inhibition of angiogenesis. This

rejection would be obviated if the tumor-bearing mice of Shultz et al, are not same as "a patient in need thereof" in claim 91.

The rejection of claims 91-94, and 98-100 rejected under 35 U.S.C. 102(e) as being anticipated by US 6783760 B1 (the effective filing date of Jul. 12, 1999) as evidenced by Stambolic et al., 1998, Cell, vol. 95, pages 29-39 is **withdrawn** because the amended claims are no longer anticipated by the prior art of record.

Double Patenting

The terminal disclaimer filed on 12/03/2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,777,439 has been reviewed and is accepted. The terminal disclaimer has been recorded. The rejection of the claims on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,777,439. is **withdrawn**.

The Following is New Grounds of Rejection

Claim Rejections - 35 USC § 103

Claims 93, 94, 99, 100, 105, and 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al., as applied to claim 91 above, and further in view of US 6783760 B1 of record.

This rejection is made because Schultz et al., teach that Wortmannin has been used to treat tumor and US 6783760 B1 teach etoposides has also been used to treat tumor. Combining two known anti-cancer treatments treating cancer is obvious.

Allowable Subject Matter

Claims 120 and 121 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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